

SPL Process ER/DL Meeting

Meeting Minutes

March 26, 2014

Chair of today's meeting: Pat Cowall-Hanover

Teleconference information:

USA Toll-Free 866-213-2145

USA Paid/International: 609-454-9913

Access code: 273 8216

Teleconference information: How to mute/unmute

#6: Mute

*6: Unmute

Link to the SPL wiki:

<http://spl-work-group.wikispaces.com/share/view/51351516>

Agenda:

1. Drug listing – “do we need to drug list samples?” (Virginia Hogan)
 - Discuss email response to the question sent to the eDRLS Team regarding Samples in DM
“While it is not a legal requirement, CDER requests firm to submit information on drug samples included on the marketed drug listing SPL.

Meeting Discussion:

- eDRLS response is consistent with our standard practice. Many companies have been drug listing samples since paper days.
- We confirmed that it isn't a requirement.
- Not in How Supplied section, but is in the drug listing.
- Anyone know what the benefit is of having this in the drug listing?
 - i. Import them if they are manufactured overseas.
- Does this apply to OTC samples?
 - i. One company did have product held up at customs when it wasn't drug listed.

2. Manufactured exclusively for private label distributors

- Requirement for drug listing under “Manufactured exclusively for private label distributor” (Mona Desai-Interchem)
- I have recently been contacted by a third party that GSK makes a product for. They have requested that we create a drug listing with the category of for Private Label Distributer. They are saying that an inspector at the port is requesting that the manufacturer have a drug listing as well as the distributor/NDA holder. Has anyone else had this request? (Ben Harpster – GSK)

Meeting Discussion:

- This is not a new process. We discussed this several years ago at a teleconference with FDA. The intent is to provide a way to clearly identify supply chain for the final product.
- The private label distributor may only know that their product is manufactured by the third party manufacturer....so this was what they were including in their SPL. Regulations clearly say that the manufacturer is responsible for drug listing. So, in order to get the complete supply chain, eDRLS established this marketing category to allow manufacturer
- Other manufacturing companies have had product held up at customs when the manufacturer hasn't submitted their finished product drug listing. Even for companies when their third party manufacturer is owned by the same company – for import purposes.
 - i. Private label drug listing: complete
 - ii. Manufactured exclusively for private label – includes only PDP and manufacturing supply chain. Need to have the manufacturers specific labeler code
 - iii. This seems to be a new import process – within the last 6 months.
- Other companies have pushed back compliance officers said that they need to see the labeler code of the manufacturer.
- Everything is exactly the same, except:
 - i. Product names are the same
 - ii. Do not need full content of labeling.
 - iii. Marketing type is “approved drug product....exclusively for private label distributor”.
 - iv. Registrant is whoever is submitting it.
 - v. For the PDP you use a finished good carton.
 - vi. For the drug product data, NDC is the manufacturer's NDC.
 - vii. Market start date can be a future date if the product has not yet been marketed.
- If the product is unapproved....and you drug list it....do you then go back and drug list it as an approved product? Then how do you delist the unapproved ASK LONNIE
 - i. You can only make 1 shipment if it is being imported under a PLAIR. We don't think that this would
- Does anyone know why the import officers are now starting to implement this. This seems to be duplicate reporting requirement.
 - i. Import compliance officers are now starting to use SPL data more.
 - ii. This has been a requirement for bulk API for a long time. This seems to now being enforced for finished product too.
 - 1. Note: the API supplier doesn't get populated in their import databases unless you do a separate API listing.

- iii. Some companies are not doing this and are not having problems, while other companies have started having problems recently.
- iv. How do they tie the finished product listing SPL with the manufactured for private labeler SPL. ASK LONNIE or eDRLS
- Note: one company also had issues with reimporting an API that had not been drug listed.

3. OTC – artwork in CCP (Robb Wirt – allergan)

- We have been having a new issue that just started this year. It has to do with CPPs. When we submit a CCP for an OTC product, the Consumer Safety Officer at the FDA is rejecting it because the artwork attached to the CPP doesn't match the JPG in the Drug Listing.
- OTC products changing artwork routinely, but the Drug Facts table never change. We did just a new person, as the last person retired. We are not sure if regulation changed, or if it's a new person learning curve. We have spoken to the FDA, and the conversation really didn't go anywhere, so another call has been set up. We are just slightly perplexed because the Drug Listing is supposed to be "representative" labeling, which it is. Artwork will not always match, as we have many sizes, and only one JPG is shown in the Listing.

Meeting Discussion:

- CPPs are certificate of pharmaceutical product – needed for free sale certificates. (used to export to other markets without doing the full registration).
- The actual labeling may be different because they may have different pack size.
- GSK, Abbott, and Merck has had CPPs rejected for this reason for the last year. They needed to hold artwork changes until after CPP was accepted – this seemed to take care of the situation. (Takes between 4 and 8 weeks.)
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4. Formatting – MSWord (Rita Wherry-astrazeneca)

- Within the last couple of weeks we have had 2 different reviewers come back to us and request formatting changes on our "Word" file. Now our SPL displays properly (because of the style sheet), however when we convert to word some of the spacing may be off and they are being sticklers for formatting. Has anyone else experienced this?

Meeting Discussion:

- Their software converts SPL to MSWord when needed. It causes minor format discrepancies (super/subscripting, footnotes, etc).
- Others are getting feedback from FDA on MSWord documents – on formatting.
- Lonnie has said that the goal is for SPL to be the standard in the future. If you have issues, you may forward these to Lonnie – so that he can use these as examples for the future.
- One company creates the MSWORD file and uses a software vendor to create the SPL. They are finding that the IE view removes spaces.

5. How to represent package layouts in the SPL for blister packs (Mike Aiken - boehringer-ingelheim)
 - Lonnie wants us to change the way we have been describing our blister packs and we are not sure why. We have been doing it the same way for yrs. I have looked at different SPL's on Daily Med and have found different ways of describing the same thing. See below for examples.)

Meeting Discussion:

- Per Lonnie, when a carton is intended to be used as a package of individual doses, each individual dosage unit should be represented in the DPL as a unit dose (1 capsule/tablet in 1 blister pack). This situation is also described in the definitions of package types on the SPL resource page.

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm163380.htm>

BOX, UNIT-DOSE	A box that contains a single dose of a non-parenteral drug product. [Note: Boxes that contain 100 unit dose blister packs should be classified under blister pack, since this is the immediate container into which the dosage form is placed.]	BOXUD	C43179
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- Each individual level of packaging should have a different NDC number. Ie the single unit dose should have a different NDC from the outer carton.
- This practice actually started a long time ago as pharma started doing this as a convenience to hospitals – ie printing a bar code on the individual blisters so that scanners could be used to verify patient medication.
- This is consistent with the bar code rule -- ie put a bar code on the individual dosage units.
- The bar code is typically consistent in number/format as an NDC code.
- This is also consistent with how these dosage units are charged to payers. Otherwise hospitals will have to make up their own NDC codes for billing purposes.

Reminder from Lonnie: Even though that the validation system does not point out data errors, it doesn't mean that your data is correct.

6. Bonus carton: 1 bottle of 100 and 1 bottle of 24. How do you do this drug list this?

Meeting Discussion:

- Drug list this as a kit – containing 1 bottle of 100 and 1 bottle of 24.

Detailed examples for topic 5 above: "How to represent package layouts for blister packs in a carton in the SPL".

Lonnie wants us to change the way we have been describing our blister packs and we are not sure why. We have been doing it the same way for yrs. I have looked at different SPL's on Daily Med and have found different ways of describing the same thing. See below for examples.

The examples below show the packaging configuration when the blister and carton share the same NDC (This is how we do it. Our blister and carton share the same NDC.):

[INVOKANA](#)

Packaging		
#	Item Code	Package Description
1	NDC:50458-140-30	30 in 1 BOTTLE
2	NDC:50458-140-90	90 in 1 BOTTLE
3	NDC:50458-140-50	500 in 1 BOTTLE
4	NDC:50458-140-10	10 in 1 CARTON
4		10 in 1 BLISTER PACK
5	NDC:50458-140-01	5 in 1 BOTTLE

16 HOW SUPPLIED/STORAGE AND HANDLING

INVOKANA (canagliflozin) tablets are available in the strengths and packages listed below:

100 mg tablets are yellow, capsule-shaped, film-coated tablets with "CFZ" on one side and "100" on the other side.

NDC 50458-140-30	Bottle of 30
NDC 50458-140-90	Bottle of 90
NDC 50458-140-50	Bottle of 500
NDC 50458-140-10	Blister package containing 100 tablets (10 blister cards containing 10 tablets each)

300 mg tablets are white, capsule-shaped, film-coated tablets with "CFZ" on one side and "300" on the other side.

NDC 50458-141-30	Bottle of 30
NDC 50458-141-90	Bottle of 90
NDC 50458-141-50	Bottle of 500
NDC 50458-141-10	Blister package containing 100 tablets (10 blister cards containing 10 tablets each)

[FARXIGA](#)

Packaging

#	Item Code	Package Description
1	NDC:0003-1427-11	30 in 1 BOTTLE, PLASTIC
2	NDC:0003-1427-12	90 in 1 BOTTLE, PLASTIC
3	NDC:0003-1427-13	500 in 1 BOTTLE, PLASTIC
4	NDC:0003-1427-14	10 in 1 CARTON
4		10 in 1 BLISTER PACK
5	NDC:0003-1427-91	1 in 1 CARTON
5		7 in 1 BLISTER PACK

16 HOW SUPPLIED/STORAGE AND HANDLING

How Supplied

FARXIGA (dapagliflozin) tablets have markings on both sides and are available in the strengths and packages listed in Table 14.

Table 14: FARXIGA Tablet Presentations

Tablet Strength	Film-Coated Tablet Color/Shape	Tablet Markings	Package Size	NDC Code
5 mg	yellow, biconvex, round	"5" engraved on one side and "1427" engraved on the other side	Bottles of 30 Bottles of 90 Bottles of 500 Hospital Unit Dose Cartons of 100	0003-1427-11 0003-1427-12 0003-1427-13 0003-1427-14
10 mg	yellow, biconvex, diamond-shaped	"10" engraved on one side and "1428" engraved on the other side	Bottles of 30 Bottles of 90 Bottles of 500 Hospital Unit Dose Cartons of 100	0003-1428-11 0003-1428-12 0003-1428-13 0003-1428-14

The examples below show the packaging configuration when our blister and carton do not share the same NDC (This is how Lonnie wants us to do it. Our blister and carton **do not** share the same NDC.):

ZORTRESS

Packaging

#	Item Code	Package Description
1	NDC:0078-0417-20	60 in 1 BOX
1	NDC:0078-0417-61	1 in 1 BLISTER PACK

PRINCIPAL DISPLAY PANEL

Package Label – 0.25 mg

Rx Only NDC 0078-0417-20

Zortress® (everolimus) Tablets

0.25 mg per tablet

Dispense With Medication Guide Enclosed or Provided Separately.

Contents:

6 blister cards of 10 tablets each

NDC 0078-0417-20

Rx only

PIOGLITAZONE

Packaging			
#	Item Code	Package Description	
1	NDC:0781-5420-64	30 in 1 BOX, UNIT-DOSE	
1	NDC:0781-5420-06	1 in 1 BLISTER PACK	
2	NDC:0781-5420-31	30 in 1 BOTTLE	
3	NDC:0781-5420-92	90 in 1 BOTTLE	
4	NDC:0781-5420-10	1000 in 1 BOTTLE	

16 HOW SUPPLIED/STORAGE AND HANDLING

Pioglitazone Tablets, USP are available are available as follows:

15 mg tablet: white, oval shaped tablets debossed with 'SZ 244' on one side and 15 on the other side.

NDC 0781-5420-31, bottle of 30 tablets

NDC 0781-5420-92, bottle of 90 tablets

NDC 0781-5420-10, bottle of 1000 tablets

NDC 0781-5420-64, carton of 30 tablets (3 x 10 Unit-Dose)
